



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Olympus Optical Co., Ltd.  
% Ms. Laura Storms-Tyler  
Director, Regulatory Affairs  
Olympus America, Inc.  
Two Corporate Center Drive  
Melville, NY 11747-3157

JUL 27 2015

Re: K021179

Trade/Device Name: Olympus Disposable Guidewire, Models G-205-3545S and  
G-205-3545A

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: II

Product Code: OCY

Dated (Date on orig SE ltr): April 11, 2002

Received (Date on orig SE ltr): April 15, 2002

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of July 5, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021179

Device Name:

Disposable Guidewire G-205-3545S, G-205-3545A

Indications for Use:

This instrument has been designed to be used with Olympus Endo-therapy Accessories. The instrument is used as guidewire of endoscopic accessories for biliary duct, including not only common bile but cystic, pancreatic, right and left hepatic ducts

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-

Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C. Brogdon  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K021179

JUL 5 2002

SMDA 510(k) SUMMARY

10621179

**A. Submitter's Name, Address, Phone and Fax Numbers**

1. Submitter's Name

Name & Address of manufacturer: Olympus Optical Co., Ltd.  
2-3-1 Shinjuku Monolis Nishi-Shinjuku,  
Shinjuku-ku Tokyo, 163-0914 Japan

8010047

2951 Ishikawa-Cho,  
Hachioji-shi, Tokyo 192-8507  
Japan

TEL 81-426-42-5177

FAX 81-426-46-5613

2. Manufacturer site/Sterilization site

Name & Address of manufacturer:

Ashitaka Factory of Terumo Corporation  
150, Mainmaigi-cho, Fujinomiya-City  
Shizuoka, 418-0015, Japan

9681834

Registration No. □

**B. Name of Contact Person**

Name:

Ms. Laura Storms-Tyler

Address, Phone and Fax Numbers:

Olympus America Inc.

Two Corporate Center Drive  
Melville, New York 11747-3157

TEL: (631) 844-5688

FAX: (631) 844-5416

**C. Device Name, Common Name, Classification Name and Predicate Devices**

Trade Name:

Disposable Guidewire G-205-3545S, G205-3545A

Common Name:

Guidewire

Classification:

Endoscope and accessories 21 CFR 876.1500

Predicate Device:

Guide Wire G35-2LB (Olympus Optical Co.,Ltd.)  
#K933110

Climber (Terumo)  
#K971937

Lagwire 5658-1/5659-1 (Boston Scientific)  
#K922302

**D. Description of the Device(s)**

G-201-35-45, G-202-35-45 are resin-treated coated guidewires. Removal of the guidewire is not necessary during sphincterotomy. G-201-35-45 is straight distal portion type, G-202-35-45 is angled distal portion type. These instruments have been designed to be used with Olympus Endo-Therapy Accessories, which are applicable for φ0.89mm (0.035 inch) diameter guidewires. These instruments are equipped with Laser-markers at the distal portion to conform guidewire placement under fluoroscopy endoscopic maneuvering.

**E. Intended Use of the Device(s)**

This instrument has been designed to be used with Olympus Endo-therapy Accessories.

The instrument is used as guidewire of endoscopic accessories for biliary duct, including not only common bile but cystic, pancreatic, right and left hepatic ducts

**F. Summary including Conclusions drawn from Non-clinical Tests**

When compared to the predicate device, Disposable Guidewire G-205-3545S, G-205-3545A does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.